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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,500	05/26/2006	Anne Mette Buhl Hertz	55320.001041	7327

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EXAMINER

GUSSOW, ANNE

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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07/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,500	Applicant(s) HERTZ ET AL.	
	Examiner ANNE M. GUSSOW	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-66 is/are pending in the application.
- 4a) Of the above claim(s) 48,51,52,55-60 and 65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-47,49,50,53,54,61-64 and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. No claims have been amended.

Claims 61-66 have been added.

Claims 48, 51, 52, and 55-60 remain withdrawn.
2. Claims 43-47, 49, 50, 53, 54, and 61-64, 66 are under examination.
3. Applicant's comments regarding the restriction requirement have been entered into the record however, they will not be addressed further because the restriction requirement was made final in the previous office action.
4. Regarding the search of additional species, although the species is free of the prior art, the claims remain rejected (see arguments below) and thus the elected species is not allowable. Therefore, additional species have not been searched and claim 65 is withdrawn from consideration as being drawn to a non-elected species.

Objections Withdrawn

5. The objections to the specification are withdrawn in view of applicant's amendments to the specification.

Rejections Maintained

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The rejection of claims 43-47, 49, 50, 53, and 54 and newly added claims 61, 63, 64, and 66 under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained.

Applicant's response filed April 21, 2008 has been carefully considered but is deemed not to be persuasive. The response states that the data shown in figure 3 of the present application clearly establishes that Applicants are in possession of and sufficiently describe a method of reproducibly detecting AMB-1 transcripts in cell extracts by means of Northern blotting, described in [0247]. It should be noted that in this Figure the left hand lanes UPN1, UPN4, and UPN7 are samples from B-CLL patients with un-mutated IgVH genes, whereas the lanes UPN19, UNP9, UPN10, UPN13, and UPN21 are samples from B-CLL patients with mutated IgVH genes. On the right are samples from tissues of healthy persons. The blot is probed with a fragment of Exon 3 (SEQ ID No: 16). The data clearly confirms the presence of at least three transcripts in samples of subtype of B-cells with un-mutated IgVH genes - one transcript with a size less than the 1.8 kb (18S RNA marker), another larger transcript between the 1.8 kb 18S RNA marker and another transcript below the 5.0 kb 28S RNA marker. The third long transcript in the top of the blot corresponds to the primary un-spliced. This Northern blot confirms that transcripts comprising Exon 3 correlate to and may be

detected in B-CLL patients with un-mutated IgVH genes. On the other hand, transcripts comprising Exon 3 is not detected in samples from B-CLL patients with mutated IgVH genes and samples from tissues of healthy persons. Thus, the presence of AMB-1 transcripts comprising Exon 3 (SEQ ID No: 16) correlates to the presence of B-cells with un-mutated IgVH genes (see response pages 10-12).

In response to this argument, the northern blot data in Figure 3 was probed with a region of Exon 3, thus detecting the Exon 3 region of RNA expressed in various samples. In this instance, the transcript was detected in mutated B-cell patients but not in unmutated B-cell patients. Thus, detection of Exon 3 identifies a subpopulation of B-cell patients, but there is no evidence that the entire transcript of SEQ ID No. 11 is absent from B-cell patients or a subtype of B-cell patients. Since the blot does not include any control samples or markers it is unclear exactly what the different transcripts are that are identified by the Exon 3 probe.

Additionally, as set forth in the previous office action, the sequences of SEQ ID Nos. 12-18 when aligned with SEQ ID No. 11 do not produce a consensus sequence, therefore detection of SEQ ID No. 11 would not necessarily detect a region of SEQ ID Nos. 12-18.

Therefore, after a fresh consideration of the claims and the evidence provided the rejection is maintained.

Conclusion

8. No claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1643

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

July 9, 2008

/David J Blanchard/
Primary Examiner, Art Unit 1643